



# A RANDOMIZED CONTROLLED CLINICAL STUDY TO COMPARE THE EFFICACY OF CHAMPAKABEEJA KALKA AND CHAMPAKABEEJA TAILA IN PADADARI

Dr. Renju. S

Associate Professor in the Dept. of Rasa Sastra and Bhaishajya Kalpana, S.C.P.M Ayurveda Medical College and Hospital, Haripur, Gonda, Uttar Pradesh

## ABSTRACT

Padadari is one of the commonest & most negligible diseases. It is observed that people are least bothered about their feet than their face. Padadari is a disease which hinders the free walking of the individual. In Ayurvedic classics, it is explained under Kshudra roga. Cracked feet also known as heel fissures is a common foot problem characterized by yellowish color of the skin on the heel of the foot, hard skin growth, hardening and cracks in the feet associated with pain, bleeding or itching. Champaka tree is highly venerated by the Hindus, and is dedicated to Lord Vishnu. It is celebrated for the exquisite perfume. Flowers are used by ladies as adornments. The effect of champaka seeds in padadari is described in modern ayurveda texts. A randomized controlled clinical study has been conducted to compare the efficacy of Champaka beeja kalka and Champakabeeja taila in Padadari. In this study prevalence of the disease was seen more in farmers and house wife, mixed diet, vatapitta prakriti people. Working in muddy area and used to long walking daily with bare foot where the major causative factor for padadari noted in the study. Cracks associated with pain, discoloration and itching were found as common presenting complaints. Clinical study showed significant relief on both trial drugs in healing padadari. Statistical results showed highly significant in pain, bleeding and itching. But there was moderate improvement in reduction of length of the crack. Both the trial drugs were found effective clinically, but comparatively Champaka beeja taila is more effective than Champaka beeja kalka.

**KEYWORDS:** Padadari, Champakabeeja, Champakabeeja Taila

## INTRODUCTION

The skin on our feet is naturally dry, unlike the skin on rest of the body. The skin of our feet has no oil glands, so it relies on hundreds of thousands of sweat glands to keep feet moisturized.<sup>[1]</sup> In Ayurveda, Padadari is described in Kshudra roga by Sushruta, Madhavanidana, Bhavaprakasha, Yogaratnakara etc. The signs, symptoms, pathogenesis and treatment of Padadari are mentioned in details which indicate that this disease was affecting the people since ancient times. From the references available in Ayurveda we learn that Acharya Sushrutha was probably the first person to describe. Excessive walking and lack of moisture on foot were the vata gets aggravated, locally deranged and produces fissures in sole.<sup>2</sup> In the initial stage of disease patient does not have any complaint. But as the disease progresses, it can lead to severe symptoms as acute pain, burning sensation, itching and even bleeding from cracks. In case of Padadari, Siravyadha, Sweda, Abhyanga, lepa are advised as treatment modalities. In this study Lepa is selected. Champaka tree is highly venerated by the Hindus, and is dedicated to Lord Vishnu. It is celebrated for the exquisite perfume. Flowers are used by ladies as adornments.<sup>3</sup> The effect of champaka seeds in padadari is described in modern ayurveda texts.

## AIM & OBJECTIVES

- To study literatures regarding the drug Champaka (*Michelia champaca Linn.*)
- To study literatures regarding the disease *Padadari*.
- To evaluate the efficacy of Seeds of Champaka (*Michelia champaca Linn.*) clinically.

## REVIEW OF LITERATURE

### Drug Review- Champaka:

The reference regarding this drug could not be traced out in Vedas. In Sushruta Samhita, it is mentioned under a type of wound smell (Su.28/11), it is mentioned under normalization of deranged water (Su.45/12), mentioned under pushpa varga (su.46/283), mentioned under Mahasugandhiyoga visha chikitsa (ka./20) and also mentioned under Mahakalyanaka ghrita for jwara chikitsa (Ut.39/232). In Ashtanga Sangraha, mentioned guna karmas in Dvividhaushadha vijnaniya (Su.12/80). In Ashtanga Hridaya, it is mentioned as one of the ingredients in Campakakhaya agada (Ut.37/71). In Bhaishajya rathnavali, it is mentioned how to collect good champaka flower in 26/498. It is one of the ingredients in Chandanabalalakshadi taila in jwarachikitsa prakarana in 5/1382 and it is One of the ingredients in Chandanabalalakshadi taila in rajayaksma prakarana in 14/314.

### BOTANICAL IDENTITY <sup>[4]</sup>

Botanical name: *Michelia champaca Linn.*

Family Name: *Magnoliaceae*

Kingdom	Plantae
Division	Angiosperms
Class	Magnoliids
Order	Magnoliales
Family	Magnoliaceae

Sub family	Magnolioideae
Genus	Michelia
Species	Champaca

**Table No.1 Showing Taxonomical classification of Michelia champaca Linn.<sup>[5]</sup>**

### Clinical Study

Clinical study was done to establish the efficacy of drug in padadari. This is an effort to prove Ayurvedic remedy for foot crack, where champaka beeja was not separately mentioned in our classics.

### MATERIALS AND METHODS

#### Preparation of drug:

1) **Champaka beeja kalka:** Raw drug Champaka seeds are collected from champaka tree at a park in Kodungallur area, Kerala. Drug cleaned from foreign matter and pulverized into kalka. And packed into packets containing 40gm each of Champaka beeja kalka.



Photo No. 1 Showing Champaka beeja kalka.

#### 2) **Champaka beeja taila<sup>[6]</sup>**

Ingredients for Champaka beeja taila preparation:

Sl. No	Ingredient	Quantity
1	Kalka Dravya- Champaka beeja	1Kg
2	Sneha Dravya- Tila taila.	4 litres
3	Drava Dravya – Water	16 litres

**Table No 2: showing proportion of quantity taken according to Sharangadhara Samhita**

#### Procedure:

Vessel was heated to remove moisture from vessel. Then tila taila was poured. Madhyamagni maintained till completion of Sneha Paka. The bolus of Kalka was added to Drava Dravya was added to Taila. Again, heat was applied with intermediate stirring. Heating process was carried out till Sneha Siddhi Lakshana was appeared then vessel was taken out from the fire and Taila was filtered through clean cloth in its hot stage. Filtered Champaka Taila was stored in a glass bottle after cooling.



**Photo No.2 Showing the preparation of Champaka beeja taila.**

#### Method of Collection of Data

After keen examination the patients having only padadari, fulfilling the inclusion criteria and not falling under exclusion group are selected. They are randomly divided into two groups comprising 15 patients in each.

	GROUP-A	GROUP-B
Sample size	15 patients	15 patients
Drug	Champaka beeja kalka	Champaka beeja taila
Matra	Quantity sufficient	Quantity sufficient
Method	External application	External application
Time	Morning & Bed time	Morning & Bed time
Duration	14 days	14 days
Follow up	On 21 <sup>st</sup> day	On 21 <sup>st</sup> day

**Table No. 3: showing study design**

#### (a) Procedure of drug administration

**Group A:** 15 patients of this group are treated with Champaka beeja kalka lepa.

**Group B:** 15 patients of this group are treated with Champaka beeja thaila.

No drug is administered orally. In group 1 and 2 anointing of affected part is done externally with Champaka beeja kalka & champaka beeja thaila respectively, twice daily for 14 days.

#### (b) Observation period

Observation and recording of the feature are done one's just prior to the treatment and then 14th day & follow up on the 21<sup>st</sup> day.

#### (c) Inclusive criteria:

- Patients who have cracks on the foot (single or both).
- Age- 20 - 65yrs.
- Both the sex will be included.

#### (d) Exclusive criteria:

- Suffering from any systemic and dreadful diseases.
- Suffering with diabetes mellitus, psoriasis, athlete's foot

- Patients with infection and oozing.

#### (e) Diagnostic criteria

The clinical features of padadari as mentioned in classics are taken as the criteria for diagnosis.

#### (f) Assessment criteria

The features of the disease padadari are classified as subjective and objective. Each of them is given gradation. Assessment of the response to the treatment is made by the study of the features periodically.

Subjective	Objective
Pain	Discoloration
Bleeding	Length of the crack
Itching	Pictorial representation
Cracks	-

**Table no 4: Showing Subjective and Objective criteria**

#### Laboratory investigations

Blood routine if necessary.

#### Grading Pattern in Padadari

##### Subjective criteria:

Grading	Symptom	
0	No pain	No pain
1	Mild	pain while walking and work without affecting gait and work
2	Moderate	pain while walking and work which affects gait and work
3	Severe	pain while walking, work and rest which affects gait and work causing limping

**Table No. 5: showing grading of Pain**

Grading	Symptom	
0	No cracks	No cracks
1	Mild	Only edges of the heel or palm or both with superficial fissure
2	Moderate	Throughout the foot or palm or both with deep fissure
3	Severe	Throughout the foot or palm or both along with clefts of toe and figure with deep fissure

**Table No. 6: showing grading of Cracks**

Grading	Symptom
0	Absent
1	Present

**Table No. 7: showing grading of Bleeding**

Grading	Symptom
0	Absent
1	Present

**Table No. 8: showing grading of Itching**

Grading	Symptom
0	Absent

1	Present
---	---------

**Table No. 9: showing grading of Discolouration**

Grading	Symptom	
0	No crack	0
1	Small	1-2cms
2	Medium	2-4cms
3	Large	4 and above

**Table No. 10: showing grading of Length of cracks**

#### Assessment of Total Effect of Therapy

<24 % relief in signs and symptoms	Poor Response
25-49 % relief in signs and symptoms	Mild Response
50-74 % relief in signs and symptoms	Moderate Response
75-100 % relief in signs and symptoms	Marked Response

**Table No. 11: showing Assessment of total effect of therapy**

#### Statistical Analysis

**Wilcoxon Signed Ranks Test** and **Mann-Whitney Test** has been used for analysing the data obtained during the study between the groups A and group B. ‘P’ value  $>0.05$  is considered statistically non-significant,  $<0.05$  is considered as statistically significant, ‘P’ value  $<0.001, <0.01$  is considered as highly significant.

#### DISCUSSION

##### Clinical Study

Keeping in mind the inclusion and exclusion criteria’s, the present study, clinical evaluation of *Champaka* in padadari was done on 30 patients. They were divided into two groups consisting of 15 patients each.

Group A were treated with *Champaka beeja kalka*.

Group B were treated with *Champaka beeja taila*.

The patients were asked to apply sufficient quantity of medicine twice a day for 14 days. The results of both trial groups were compared and analysed by doing statistical analysis by following the Wilcoxon Signed Ranks Test & Mann-Whitney Test.

#### Interpretation of result

The results of the present study were taken from the collected data according to variable pain, cracks, etc. the data were collected before treatment, after treatment and after follow up .it is observed that the features like bleeding, length of the crack, itching, discolouration and even pain were asymmetrical in both the feet. Hence could not be taken for comparison individually for the study effect of treatment over them. So, the results were drawn with the average of observations of two feet.

**In case of Pain**, group 1 got 73 % result after treatment. In case of group 2, got 80% result after treatment. Further the reduction in both the group was statistically highly significant as assessed by the Wilcoxon Signed Ranks test. This observation proves

that both the treatment are highly effective in relieving pain. The comparison of the therapeutic effects in these two groups reveal that p value is 0.757, no significant difference seen (p value >0.05).

**In case of Cracks,** group 1 having 86.67% of moderate cracks before treatment and after treatment reduces to 80% mild cracks, group 2 having 66.67% of moderate cracks before treatment and after treatment reduces to 73.33% mild cracks. Further the reduction in both the group was statistically highly significant as assessed by the Wilcoxon Signed Ranks test. The comparison of the therapeutic effects in these two groups reveal that p value is 0.715, no significant difference seen (p value >0.05).

**In case of Bleeding,** both the groups got 100% result after treatment. Further the reduction in both the group was statistically highly significant as assessed by the Wilcoxon Signed Ranks test. This observation proves that both the treatment is highly effective in relieving bleeding. The comparison of the therapeutic effects in two groups reveal that p value is 1.00, no significant difference seen (p value >0.05).

**In case of Itching,** both the groups got 100% result after treatment. Further the reduction in both the group was statistically highly significant as assessed by the Wilcoxon Signed Ranks test. This observation proves that both the treatment is highly effective in relieving itching. The comparison of the therapeutic effects in two groups reveal that p value is 1.00, no significant difference seen (p value >0.05).

**In case of Discoloration,** both the groups got 100% result after treatment. Further the reduction in both the group was statistically highly significant as assessed by the Wilcoxon Signed Ranks test. This observation proves that both the treatment is highly effective in relieving discoloration. The comparison of the therapeutic effects in two groups reveal that p value is 1.00, no significant difference seen (p value >0.05).

**In case of Length of the crack,** group 1 reduced smaller crack 100% result after treatment. In case of group 2 result got 93.33% result after treatment. Further the reduction in both the group was statistically significant as assessed by the wilcoxon signed ranked test. This observation proves that both the treatment is effective in decreasing length of the crack. The comparison of the therapeutic effects in two groups reveal that p value is 0.317, no significant difference seen (p value >0.05).

#### Mode of action

In padadari, the aggravated vata dosha localized on pada to cause the Sputana, Ruja and Rukshata. Champaka beeja drug by the virtue of its Snigda guna relives vata dosa, does mardavakara and varnya; Pichila guna does lepana and sandana karma and ushna guna acts as vata shamaka and ruja hara.

Medicated Snehas have a better pharmacokinetic action in comparison to other dosage forms because of the lipid nature of the bio membrane of human body. Sneha is unique therapeutic media which can serve in all routes of administration as

systemically and topically because of its high absorption rate and sustained release.

#### CONCLUSION

Padadari is one of the kshudra roga because one which are comparatively less severe than other diseases. Acharya Sushruta described about padadari under kshudraroga. In this study prevalence of the disease was seen more in farmers and house wife, mixed diet, vatapitta prakriti people. Working in muddy area and used to long walking daily with bare foot where the major causative factor for padadari noted in the study. Cracks associated with pain, discolouration and itching were found as common presenting complaints. In the present study, preparation of Champaka beeja kalka was easy than Champaka beeja taila. Here Champaka beeja taila was found easy to administer and was user friendly. Clinical study showed significant relief on both trial drugs in healing padadari. Statistical results showed highly significant in pain, bleeding and itching. But there was moderate improvement in reduction of length of the crack. Both the trial drugs were found effective clinically, but comparatively Champaka beeja taila is more effective than Champaka beeja kalka.

#### REFERENCES

1. www.footvitals.com
2. Vaidya Jadavji Trikamji Acharya, Susruta Samhita with the Nibandhasangraha Commentary of Sri Dalhanacharya and the Nyayachandrika Panjika of Sri Gayadasacharya on Nidanasthana. Choukambha surabharati prakashan Varanasi , Reprint2008. 13/29 pg no 321, 1/6 pg no 396.
3. Colonel Heber Dury- The useful plants of India, published by Allied book centre, 2nd edition, reprint 1991, P-202, Pp-51.
4. Kirtikar K.R, Major Basu B.D.-Indian Medicinal Plants ,Edited by E Blater, J.F.Caicus and K.S MHaskar published by, International book distributors, Allahabad,2nd edition, vol 1,P-54-58,Pp-2393.
5. Kapildev dwivedi. Vedo me Ayurveda. Vishwabharati Anusandhana Parishad, Varanasi. Edition: 1993. Pp-296 p-74
6. Mishra Siddhinandan, Bhaishajya Ratnavali of Govind Das Sen. 1st ed, Varanasi, Chowkhambha surabharati prakashan, 2013 Edition. Kushtarogadhikara/260, Page No. 885.